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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,975	03/15/2005	Helene Le Buannec	0510-1230	7511

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EXAMINER	
WOODWARD, CHERIE MICHELLE	
ART UNIT	PAPER NUMBER
1647	

NOTIFICATION DATE	DELIVERY MODE
01/22/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No.	Applicant(s)	
	10/527,975	LE BUANNEC ET AL.	
	Examiner	Art Unit	
	CHERIE M. WOODWARD	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 11-28* is/are pending in the application.

4a) Of the above claim(s) *11-20 and 26-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 21-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/1/2009 has been entered.

Formal Matters

2. Claims 4-10 and 29 have been cancelled by Applicant. Claims 1-3 and 11-28 are pending. Claims 11-20 and 26-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected inventions, there being no allowable generic or linking claim. Claims 1-3 and 21-25 are under examination.

Advisory Notice - Inventorship

3. In the Response to Denial of Request for Power of Attorney, filed 8/25/2009, Applicant argues that inventors Cohen and Peltre have were deleted by the International Bureau on 1/28/2008 and 4/11/2005 via form PCT/IB/306. Applicant states that copies of the IB forms were enclosed. However, the IB forms were not enclosed and there is no record of the IB change of inventorship in the file wrapper. For a change of inventorship in a nonprovisional application filed under 35 USC 371, Applicant is referred to 37 CFR 1.48(f), 1.47(a)(4) and 1.497(d) and (f).

If the oath or declaration filed pursuant to 35 U.S.C. 371(c)(4) and this section names an inventive entity different from the inventive entity set forth in the international application, or if a change to the inventive entity has been effected under PCT Rule 92 bis subsequent to the execution of any oath or declaration which was filed in the application under PCT Rule 4.17(iv) or this section and the inventive entity thus changed is different from the inventive entity identified in any such oath or declaration, applicant **must submit**:

(1) A statement from each person being added as an inventor and from each person being deleted as an inventor that any error in inventorship in the international application occurred without deceptive intention on his or her part;

(2) The processing fee set forth in § 1.17(i); and

(3) If an assignment has been executed by any of the original named inventors, the written consent of the assignee (see § 3.73(b) of this chapter); and

(4) Any new oath or declaration required by paragraph (f) of this section.

To date, none of these required documents are of record in the file wrapper. The amended Application Data Sheet, filed 8/28/2009 is noted, but it is not sufficient. Accordingly, the inventive entity of the instant application comprises: Zagury, Le Buannec, Cohen, and Peltre.

Response to Arguments

Objections/Rejections Withdrawn

4. The provisional rejection of claims 1-3 and 21-25 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25-27 of copending Application No. 11/915,044, is withdrawn in light of the cancellation of claims 25-27 in the '044 application.

5. The rejection of claim 25 under 35 U.S.C. 112, second paragraph, is withdrawn in light of Applicant's amendments.

Objections/Rejections Maintained

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3 and 21-25 remain rejected under 35 U.S.C. 102(b) as being anticipated by Zagury et al., (WO 02/011759 A1, published 2 February 2002, in French, he certified English translation of which found in US 2004/0028647 A1, the US patent application filing under 35 USC 371 PCT/FR01/02575), for the reasons of record and the reasons set forth herein.

The Declaration of Dr. Zagury, filed 6/18/2009 is noted. The sufficiency of the Declaration is discussed at length below.

As stated of record, Zagury et al., teach immunogenic compositions with an anti-cytokine effect comprising an immunogen, including TNFα conjugated to a carrier protein, including KLH (pp. 9

[corresponding to paragraphs 49 and 50 in the English translation]). The immunogenic complex of KLH and TNFα is taught using glutaraldehyde at p. 22 (see paragraph 134 of the English translation) (see also claims 1-4, 6, and 11).

Applicant argues that Zagury only discloses conjugates where the antigenic protein is exclusively linked to the carrier protein by covalent bonding (Remarks, p. 8). Applicant provides a Declaration by Zagury filed under 37 CFR 1.132 to provide testable evidence requested by the Examiner in the prior Office Actions (Remarks, p. 9). Applicant argues that there is no disclosure in Zagury of an immunogenic compound comprising both TNFα and KLH carrier (Remarks, p. 9). Applicant argues that contrary to the examiner's position, Zagury paragraph 134 does not support the proposition that glutaraldehyde is taught as the preferred bifunctional coupling reagent in an anti-TNFα vaccine conjugate (Remarks, p. 9). Applicant argues that the addition of glycine blocks any unreacted glutaraldehyde functionally to ensure that the final immunogenic product is chemically inert and insures that the product could not be coupled to KLH even if such coupling were desired (Remarks, p. 10). Applicant argues the conjugates of VEGF, EF, and IFNα were prepared in such a way that the antigenic protein and KLH are "linked exclusively or essentially exclusively through covalent bonds" and thus would be outside the scope of pending claim 1 (Remarks, p. 10). Applicant argues that the method disclosed by Zagury has four steps as exemplified by the method of conjugating VEGF to KLH (Remarks, pp. 10-11). Applicant argues that the method results in the production of immunogenic conjugates where the antigenic proteins are covalently bound to the KLH molecules and that the only possible point of attachment is by chemical reaction with the free aldehyde groups on the activated KLH (Remarks, p. 11). Applicant argues that in the testable work completed by Dr. Zagury (as Exhibit 1), all of the TNFα was covalently bound to KLH, and accordingly the conjugates prepared by the Zagury method cannot anticipate the instant claims (Remarks, p. 11). Applicant argues that the information and evidence from the Zagury Declaration show that the structural features of the conjugates of the instant invention are distinguishable from the conjugates prepared by Zagury's methods (Remarks, p. 12).

Applicant's arguments and the Declaration filed 6/18/2009 have been fully considered, but they are not persuasive. Applicant's arguments and the Declaration of Zagury contain contrary inconsistencies and multiple factually inaccurate statements.

In the Declaration at paragraph 7, Declarant states that there is no disclosure in Zagury of an immunogenic compound comprising both TNFα and KLH carrier protein molecules. This statement is factually inaccurate. TNFα conjugated to a carrier protein, including KLH (pp. 9 [corresponding to paragraphs 49 and 50 in the '647 publication, which is the English language equivalent]).

In the Declaration at paragraph 9, Declarant states that there is no disclosure in Zagury in which glutaraldehyde is used as a coupling agent. This statement is factually inaccurate. Preparation 10, paragraphs 176-180 of the '647 publication teaches using glutaraldehyde as the coupling agent for the immunogen-KLH conjugate. Declarant's paragraphs 21 and 22 also contradict Declarant's statement in paragraph 9.

Declarant's statements in paragraphs 9 and 10 that "Zagury does not actually describe a conjugate between TNFα protein molecules and KLH carrier protein molecules, nor a method for preparing the same" is not entirely factually accurate because Zagury teaches a specific, finite group of preferred immunogens, including TNFα at paragraph 50 and it teaches immunogen-KLH conjugates comprising the members of the specific, finite, preferred immunogen group prepared using glutaraldehyde as the bifunctional bond chemical agent (see KLH-VEGF at paragraphs 176-180; KLH-E7 at paragraphs 181-184; KLH-IFNα at paragraphs 185-187; and the detoxified TNFα immunogen at paragraphs 132-145).

Paragraphs 13-18 of the Declaration are drawn to a misunderstanding of the examiner's statement regarding the citation of paragraph 134 of the Zagury prior art reference. The examiner understands that paragraph 134 is drawn to the TNFα composition as a detoxified TNFα molecule that has been treated with glutaraldehyde, in the same way that the detoxified p53 immunogen was prepared. The examiner understands that paragraph 134 does not, by itself, teach a TNFα-KLH conjugate where in glutaraldehyde is used as the bifunctional bond chemical agent. The KLH conjugation step using glutaraldehyde is taught in paragraphs 176-187.

Declarant's statements in paragraph 20 that the conjugates were prepared exclusively or quasi-exclusively through covalent bonds appears to be somewhat contradictory to the teachings in Zagury disclosing the use of sulfo-SIAB and SMCC as spacer arms in joining the immunogen and carrier (i.e. KLH) molecules (see paragraphs 154, 156, 164, and 166). It may be that the spacer arms also contained covalent bonds, but the issue is not entirely relevant to the claims at issue because claim 1 requires that the bonds be covalent and that the bonds are made by using glutaraldehyde as the bond agent, which is taught by the Zagury reference as paragraphs 176-187).

Declarant's statements in paragraphs 24-30, directed to the method claims of the copending '975 application, are not relevant to the composition claims under examination.

Declarant's "understanding" in paragraph 27 as to the comparison of composition claims and the method of making the composition are factually and legally inaccurate and are not relevant as they relate to the examination of the instant patent application. The instant claims are not product-by-process claims. Even if they were, during examination product-by-process claims are not limited to the manipulations of

the recited method steps of making the composition. Rather, they are only limited by the structure of the composition. See MPEP 2113.

Declarant's statements in paragraphs 32-57 and the data in Exhibit B cannot be accepted by the examiner because the resulting compositions were not made by all of the steps taught by Zagury. Specifically, the size exclusion step was not performed. Because the final size exclusion step may affect the structure of the final composition and the examiner does not have the facilities available to determine whether the omission of the size exclusion step would materially affect the resulting composition, the Declarant's statements directed to the experiments in paragraphs 32-57 and to the data in Exhibit B cannot be accepted by the examiner. The examiner's position in this regard is substantiated by Declarant's statement in paragraph 45.

Declarant's statements in paragraphs 58-71 are not relevant to the instant claims under examination.

Regarding Applicant's argument that Zagury only discloses conjugates where the antigenic protein is exclusively linked to the carrier protein by covalent bonding, Applicant's argument is confusing and seemingly without merit because claim 1 requires that the carrier and immunogen be covalently bonded (see instant claim 1, lines 5 and 6).

Regarding Applicant's argument that the Declaration by Zagury filed under 37 CFR 1.132 provides testable evidence requested by the Examiner in the prior Office Actions, the deficiencies of the Zagury Declaration are discussed at length above.

Regarding Applicant's argument that there is no disclosure in Zagury of an immunogenic compound comprising both TNFα and KLH carrier, this statement echoes the Declaration paragraphs 9 and 10. The statement is not entirely factually accurate because Zagury teaches a specific, finite group of preferred immunogens, including TNFα at paragraph 50 and it teaches immunogen-KLH conjugates comprising the members of the specific, finite, preferred immunogen group prepared using glutaraldehyde as the bifunctional bond chemical agent (see KLH-VEGF at paragraphs 176-180; KLH-E7 at paragraphs 181-184; KLH-IFNα at paragraphs 185-187; and the detoxified TNFα immunogen at paragraphs 132-145). Declarant's paragraphs 21 and 22 also contradict Applicant's arguments.

Regarding Applicant's argument that contrary to the examiner's position, Zagury paragraph 134 does not support the proposition that glutaraldehyde is taught as the preferred bifunctional coupling reagent in an anti-TNFα vaccine conjugate, Applicant's argument is not entirely correct. Applicant's argument appears to reflect the Declaration paragraphs 13-18. Applicant's argument is drawn to a misunderstanding of the examiner's statement regarding the citation of paragraph 134 of the Zagury prior

art reference. The examiner understands that paragraph 134 is drawn to the TNFα composition as a detoxified TNFα molecule that has been treated with glutaraldehyde, in the same way that the detoxified p53 immunogen was prepared. The examiner understands that paragraph 134 does not, by itself, teach a TNFα-KLH conjugate where in glutaraldehyde is used as the bifunctional bond chemical agent. The KLH conjugation step using glutaraldehyde is taught in paragraphs 176-187.

Regarding Applicant's argument that the addition of glycine blocks any unreacted glutaraldehyde functionally to ensure that the final immunogenic product is chemically inert and insures that the product could not be coupled to KLH even if such coupling were desired, Applicant's argument is unsupported by the evidence and is contradicted by the prior art Zagury reference and the Declaration of Zagury at paragraphs 13-18. Paragraph 134 of Zagury teaches the detoxification of TNFα using glutaraldehyde and then using glycine to block free aldehyde groups. However, Preparation 10 of Zagury, for example, which describes the KLH-VEGF conjugate, was made using glutaraldehyde as the conjugating reagent. Preparation 10 describes that the excess glutaraldehyde was removed by dialysis in PBS (paragraphs 176-179). Clearly, the KLH-VEGF conjugate was created using glutaraldehyde as the conjugate coupling agent, rendering the argument of Applicant untenable.

Regarding Applicant's argument that the conjugates of VEGF, EF, and IFNα were prepared in such a way that the antigenic protein and KLH are "linked exclusively or essentially exclusively through covalent bonds" and thus would be outside the scope of pending claim 1, Applicant's argument is confusing and seemingly without merit because claim 1 in fact requires covalent bonding (see claim 1).

Regarding Applicant's argument that the method disclosed by Zagury has four steps as exemplified by the method of conjugating VEGF to KLH and that the method results in the production of immunogenic conjugates where the antigenic proteins are covalently bound to the KLH molecules and that the only possible point of attachment is by chemical reaction with the free aldehyde groups on the activated KLH, Applicant's arguments are without merit. As stated above, Declarant's statements in paragraphs 32-57 and the data in Exhibit B cannot be accepted by the examiner because the resulting compositions were not made by all of the steps taught by Zagury. Specifically, the size exclusion step was not performed. Because the final size exclusion step may affect the structure of the final composition and the examiner does not have the facilities available to determine whether the omission of the size exclusion step would materially affect the resulting composition, the Declarant's statements directed to the experiments in paragraphs 32-57 and to the data in Exhibit B cannot be accepted by the examiner. The examiner's position in this regard is substantiated by Declarant's statement in paragraph 45. Further, statements and arguments directed to the process of making the composition are not relevant to the instant

composition claims. The instant claims are not product-by-process claims. Even if they were, during examination product-by-process claims are not limited to the manipulations of the recited method steps of making the composition. Rather, they are only limited by the structure of the composition. See MPEP 2113.

Regarding Applicant's argument that in the testable work completed by Dr. Zagury (as Exhibit 1), all of the TNFα was covalently bound to KLH, and accordingly the conjugates prepared by the Zagury method cannot anticipate the instant claims, Applicant's arguments cannot be accepted for the reasons set forth above. As stated above, Declarant's statements and data cannot be accepted by the examiner because the resulting compositions were not made by all of the steps taught by Zagury. Specifically, the size exclusion step was not performed. Because the final size exclusion step may affect the structure of the final composition and the examiner does not have the facilities available to determine whether the omission of the size exclusion step would materially affect the resulting composition, the Declarant's statements directed to the experiments in paragraphs 32-57 and to the data in Exhibit B cannot be accepted by the examiner. The examiner's position in this regard is substantiated by Declarant's statement in paragraph 45. Further, statements and arguments directed to the process of making the composition are not relevant to the instant composition claims. The instant claims are not product-by-process claims. Even if they were, during examination product-by-process claims are not limited to the manipulations of the recited method steps of making the composition. Rather, they are only limited by the structure of the composition. See MPEP 2113.

Regarding Applicant's argument that the information and evidence from the Zagury Declaration show that the structural features of the conjugates of the instant invention are distinguishable from the conjugates prepared by Zagury's methods, Applicant's argument is factual, but only because the Declarant did not follow all of the method steps taught by Zagury, As stated in paragraphs 32 and 45 of the Declaration. Paragraph 45 of the Declaration specifically states that the end-product of the "testing" is not exactly the same as the final products of Zagury because of the missing size exclusion step. Because the final size exclusion step may affect the structure of the final composition and the examiner does not have the facilities available to determine whether the omission of the size exclusion step would materially affect the resulting composition, the Declarant's statements directed to the experiments and the data in the Exhibits cannot be accepted by the examiner.

The rejection is maintained for the reasons set forth above and the reasons of record.

Provisional Obvious-Type Double Patenting Rejections

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-3 and 21-25 remain provisionally rejected on the ground of nonstatutory double patenting over claims 1-4, 6-8, 10-12, 14-17, and 19 of copending Application No. 11/735,319, for the reasons of record and the reasons set forth herein.

Applicant argues that the claims of the '319 application are drawn to inactivated TNFα and are not drawn to heterocomplexes between TNFα and KLH or covalent linkages to the carrier protein (Remarks, filed 10/1/2009, p. 3). Applicants arguments have been fully considered, but they are not persuasive.

The specification of the '319 application teaches immunogen-carrier conjugates comprising TNFα as the immunogen and KLH as the carrier at paragraphs 48, 53, 58, and Figure 2. The '319 application comprises the same KLH-immunogen conjugates as the instant application (compare specifications), where the conjugates comprise covalent bonds and are conjugated using glutaraldeyhde

(see Preparation 10, paragraphs 140-148 of the '319 application). Absent evidence to the contrary, the KLH conjugates of the '319 application inherently comprise heterocomplexes.

Applicant is reminded that MPEP § 804 (II) states, "When considering whether the invention defined in a claim of an application would have been an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1279, 23 USPQ2d 1839, 1846 (Fed. Cir. 1992). This does not mean that one is precluded from all use of the patent disclosure." (Emphasis added). "Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. *In re Vogel*, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970)."

Accordingly, the provisional rejection is maintained.

Conclusion

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:30am-6:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/
Primary Examiner, Art Unit 1647